

NEW JERSEY COMMISSION ON SPINAL CORD RESEARCH



RESEARCH PROGRAM GUIDELINES

INTRODUCTION

Approximately 6,000 New Jersey residents suffer from traumatic injuries or diseases that damage the spinal cord. Approximately 300 new injuries occur each year. The economic consequences of the resulting physical disabilities are enormous. The personal toll on individuals and families with spinal cord injuries and their communities is incalculable.

Therefore, in September 1999, Governor Christine Todd Whitman signed legislation creating the New Jersey Commission on Spinal Cord Research (NJCSCR), allocating funding to the New Jersey Spinal Cord Research Fund.

The charge to the NJCSCR is:

The NJCSCR will solicit and approve support of research projects, administer the awards through research grants, and promote development of spinal cord research projects within the State of New Jersey that focus on treatments and cures. The NJCSCR will compile a research directory of all spinal cord research projects being conducted within the State, and provide the Governor and the Legislature with an annual report by January 30th of each year describing the status of the NJCSCR's activities and the results of its funded research projects.

PROGRAM OBJECTIVES

The NJCSCR is committed to accelerating research to develop effective interventions and cures for paralysis and other consequences of spinal cord injury and disease. Its primary objectives are:

- To advance the field of spinal cord repair and regeneration and the New Jersey research community by encouraging established scientists to apply their expertise to the spinal cord.
- To foster collaborative, interdisciplinary approaches to spinal cord research.
- To nurture the next generation of spinal cord researchers through support of young scientists and postdoctoral fellows.
- To prevent or treat secondary biological conditions resulting from spinal cord injury.
- To promote dissemination of the research findings generated by those scientists supported by the NJCSCR.

NJCSCR awards are intended to promote innovative, groundbreaking research, not to provide long-term support. Grantees are eligible to apply for funding for additional research projects, but all applications will be reviewed competitively.

FUNDING PRIORITIES

The New Jersey Commission on Spinal Cord Research will fund research activities that hold promise of developing effective interventions and cures for paralysis and other consequences of spinal cord injury and disease. The areas of research listed below highlight the focus of current NJCSCR emphasis and funding:

- Studying strategies to promote neuronal growth and survival, encourage the formation of synapses, enhance appropriate myelination, restore axonal conduction, replace injured cells, or otherwise improve function after spinal cord injury.
- Evaluating efficacy of drugs and other interventions that prevent or reduce secondary neuronal injury or providing insight into the mechanisms causing progressive damage.
- Defining anatomical characteristics of spinal cord injury or disease in well-defined animal models and in the human spinal cord, specifically documenting the cellular systems vulnerable to injury or disease and the functional losses which occur as a result thereof.
- Elucidating biological or physical mechanisms underlying approaches to improve functions compromised by spinal cord injury, e.g., bladder, bowel and sexual function, and alleviate chronic pain, spasticity, and severe hypertension.
- Developing strategies to prevent or treat secondary complications arising from injury or disease to the spinal cord.
- Developing innovative restorative rehabilitation strategies to promote recovery of biological function.
- Translating basic and pre-clinical findings into clinical application.
- Supporting the investigation of promising new approaches.

ELIGIBILITY

The following researchers are eligible to submit proposals to the NJCSCR for research grant awards. All applicants, organizations/institutions must be located within the State of New Jersey.

- Ph.D., M.D., or other such professionals.
- Independent investigators at any stage of professional development.
- Postdoctoral fellows, Graduate fellows.
- Established investigators new to the field of spinal cord injury research.

- Young Investigators (five years post-completion of formal training)

Collaborations between basic research scientists and clinicians with spinal cord injury experience are encouraged. Young investigators are encouraged to partner with established investigators to nurture their scientific growth.

All applicants including Principal Investigators and organizations/institutions are encouraged to collaborate with other New Jersey-based researchers as well as with researchers located out-of-state, or out of the country. Senior scientists, young investigators, postdoctoral and graduate fellows may serve as Principal Investigator. If the applicant is a fellow, he/she must submit a letter of support from the laboratory's senior scientist, as well as two other appropriate letters of reference.

PROTECTION OF HUMAN SUBJECT, ANIMAL WELFARE, AND RECOMBINANT DNA

Compliance with National Institutes of Health regulations for the protection of human subjects, animal welfare, recombinant DNA, and inclusion of women and minorities in clinical trials is required for all grants.

It is the responsibility of the applicant as a potential recipient of a NJCSCR grant to assure that the rights and welfare of all human subjects used in any NJCSCR sponsored research are protected. Any applications involving human subjects must be reviewed and approved by the appropriate institutional review board.

It is the responsibility of the applicant as a potential recipient of a NJCSCR grant to assure proper care and treatment of all laboratory animals used in any NJCSCR sponsored research. Any applications involving laboratory animals must be reviewed and approved by the appropriate institutional review committee.

It is the responsibility of the applicant as a potential recipient of a NJCSCR grant to assure that the physical and biological containment needed for research involving any recombinant DNA molecules is within policies set out in the current "National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules." Any applications involving recombinant DNA molecules must be reviewed and approved by the appropriate institutional review board.

RESEARCH GRANTS AVAILABLE

The NJCSCR offers four types of grants - Five-Year Named Chairs for Senior and Junior Faculty, One-Time Start-Up Costs Grants, Individual Research Grants, and Postdoctoral and Graduate Fellowship Grants.

Qualifying Institutions: For the purpose of all NJCSCR grants, a qualifying institution is defined as any academic institution, research organization, public or private institution or other entity, located in the State of New Jersey, with a demonstrated capability to conduct grant funded research, and specifically approved by the vote of the Commission, but in no case can an individual be a qualifying research institution.

The NJCSCR reserves the right to distribute funds among the grants in all its grant programs. The NJCSCR reserves the right not to fund any grant in any of its grant programs to the maximum amount, or not to fund any grant in any grant program at all. Between \$2,000,000 and

\$4,000,000 should be made available for all four grant programs. Funding estimates may vary, and are subject to annual appropriations.

Five-Year Named Chair for Senior and Junior Faculty Grant

The NJCSCR will fund grants totaling \$1,000,000 for a single senior faculty and \$600,000 for a single junior faculty for a Five-Year Named Chair for Senior and Junior Faculty to facilitate the recruitment of highly qualified out-of-state scientists to establish new spinal cord injury laboratories in New Jersey. The NJCSCR will also consider applications from in-State scientists in other fields proposing to shift their focus and establish new spinal cord injury laboratories in New Jersey. All qualifying institutions in the State of New Jersey may apply. The qualifying institution must provide evidence of support such as appropriate laboratory facilities and the commitment of financial support necessary to sustain the research for a minimum of five years. A qualifying research institution may not apply for both a "One-Time Start-Up Costs" grant and a "Five-Year Named Chair for Senior and Junior Faculty" grant using the same faculty member in the same grant year.

Grants will total \$1,000,000 for senior faculty and \$600,000 for junior faculty (including direct and indirect costs; a maximum of 10% may be applied to indirect costs). Successful candidates also will receive \$100,000 and \$50,000 respectively in start-up costs. The person holding this position will be called "New Jersey Professor of Spinal Cord Research."

A senior faculty candidate will have a Ph.D. and/or M.D., an outstanding record of excellence and achievement in areas relevant to spinal cord injury research, high quality publications, a national/international reputation, demonstrated leadership capabilities, evidence of sustained success in competitive science funding, and a commitment to the development of practical therapies. Experienced researchers in other fields moving to spinal cord research also will be considered.

A junior faculty candidate will have a Ph.D. and/or M.D., appropriate postdoctoral experience in a well-established research facility, and confidential recommendations from the director and senior leaders of his/her present research setting. Outside references will enhance the application.

Applications are evaluated based upon evidence provided by the qualifying institution that the proposed candidate has accepted a position and that appropriate research facilities are available or will be provided by the start date of this award.

Awards will begin on or about December 15, 2006. Money granted must be held in a separate account by the institution with all accrued interest being maintained in the account. Any change either in awardee or the research focus will result in the revocation of the award and the return of all funds on a prorated basis.

Annual funding within the five-year period will be contingent upon the availability of funds and the submission of an annual Narrative Report that is favorably reviewed by an independent scientific merit review panel. The panel's continuation recommendations will be made to the NJCSCR for funding approval. Project periods may not exceed five years. An Evaluation Form must be submitted to the NJCSCR office each year for two years following termination of a Five-Year Named Chair grant. All forms are available at www.state.nj.us/health/spinalcord/.

One-Time Start-Up Costs Grant

The NJCSCR will fund start-up costs ranging from \$250,000 to \$1,000,000 to facilitate the recruitment of out-of-state scientists to establish new spinal cord injury laboratories in New Jersey. The NJCSCR will also consider applications from in-State scientists in other fields proposing to shift their focus and establish new spinal cord injury laboratories in New Jersey. The primary focus of the research must hold promise of developing effective interventions and cures for paralysis and other consequences of spinal cord injury and disease.

All qualifying institutions in the State of New Jersey may apply. The qualifying institution must provide evidence of qualified research leadership for the new laboratory and the commitment of financial support necessary to sustain the research for a minimum of five years. A qualifying research institution may not apply for both a "One-Time Start-Up Costs" grant and a "Five-Year Named Chair for Senior and Junior Faculty" grant using the same faculty member in the same grant year.

Grants ranging from \$250,000 to \$1,000,000 will be available from the New Jersey Spinal Cord Research Fund to support the initiation of new research programs in spinal cord injury. These awards may be used for the renovation of space, support of research personnel (maximum of one year salary for technical support staff; after the first year, no personnel costs are permitted), and the purchase of equipment directly related to the research. No indirect costs are permitted. The goal of this program is to enable the establishment of new laboratories and facilitate the recruitment of highly qualified researchers to conduct spinal cord research in New Jersey.

Proposals are evaluated based upon evidence provided by the qualifying institution that a new research laboratory will be established upon receipt of these funds. Such evidence should include, but is not limited to, range of construction, detailed equipment listing, evidence of other support from the institution, evidence that the institution is providing space to be renovated, information on a newly recruited faculty or staff member, or evidence that an experienced researcher in a related field will establish a new laboratory dedicated to spinal cord injury research.

Awards will begin on or about December 15, 2006. Money granted must be held in a separate account with all accrued interest being maintained in the account. Each grant award will be contingent upon the availability of funds. Any change in the research focus will result in the revocation of the award and the return of funds on a prorated basis. This is a one-year grant award with a progress reporting period of five years during which time an annual Narrative Report must be submitted to the NJCSCR office. Evidence of the necessary organizational/institutional financial support to sustain the research must be included as part of the report. All forms are available at www.state.nj.us/health/spinalcord/.

Individual Research Grant

The NJCSCR will fund Individual Research Grants. Applicants are encouraged to apply for a one-year or two-year award. Maximum funding is up to \$200,000 per year including direct and indirect costs, (10% maximum for the latter). Successful applicants are offered the opportunity to participate in an approved spinal cord injury techniques course. The NJCSCR will make available up to \$4,000 for a grantee to attend one of the following spinal cord injury techniques courses at: Reeve Irvine Research Center, University of California, Irvine; The Ohio State University; and The W.M. Keck Center for Collaborative Neuroscience, Rutgers, The State University of New Jersey. Grantees are responsible for making all necessary travel and course participation arrangements and payments. Reimbursements will be made to those who provide proof of course completion and expense receipts.

Successful applicants are also offered the opportunity to apply for a small collaborative award supplement of up to \$5,000. This supplement will be made available to support SCI collaborations that emerge from the annual NJCSCR Symposium. All active NJCSCR Individual Research grant holders who attend the symposium are eligible to apply. For more information about this award supplement, please refer to the NJCSCR website at: www.state.nj.us/health/spinalcord/.

The goals of this program are (1) to encourage promising postdoctoral fellows and young investigators to undertake research on spinal cord regeneration, recovery and rehabilitation; (2) to encourage scientists who are well-established in other areas to transfer their efforts to spinal cord research; and (3) enable researchers with novel scientific and clinical ideas to test them and develop pilot data needed to seek larger awards from the National Institutes of Health, and other funding sources.

Principal investigators must be affiliated with a New Jersey State academic institution, research organization, public or private agency or other entity with demonstrated capability to conduct research responsibly. Senior scientists, young investigators, and postdoctoral fellows may serve as principal investigator. If the applicant is a fellow, s/he must submit a letter of support from the laboratory's senior scientist, as well as two other appropriate letters of reference. Unaffiliated individuals will not be funded. Individuals of any nationality or citizenship status may apply, provided they are employed by or affiliated with a qualified New Jersey State organization/institution.

Awards will begin on or about December 15, 2006. All qualifying institutions in the State of New Jersey may apply. Two-year awards are made through one-year contracts. Each funding award within the two-year period will be contingent upon the availability of funds. Second-year support for all Individual Research grants is contingent upon submission of a Grant Continuation Application. The Grant Continuation Application must be favorably reviewed by an independent scientific merit review panel and recommended to the NJCSCR for continued funding. An Evaluation Form must be submitted to the NJCSCR office each year for two years following termination of an Individual Research grant. All forms are available at www.state.nj.us/health/spinalcord/.

Postdoctoral and Graduate Student Fellowship Grants

Postdoctoral Fellowships are two-year awards of \$50,000 per annum. They provide an annual stipend of \$36,000, a research allowance of \$13,000, and a travel budget of \$1,000. No part of the award may be used for institutional overhead or indirect costs. Institutions may supplement stipends, but not with other full-time fellowship awards, or other NJCSCR monies. Candidates of outstanding quality must hold a Ph.D., and/or M.D., or equivalent graduate degree. Appropriate degrees must be awarded prior to activation of award. Candidates must be accepted for postdoctoral training under the supervision of an appropriate mentor at a qualifying academic research institution in New Jersey. A candidate may not apply for a NJCSCR Postdoctoral Fellowship and a NJCSCR Individual Research grant in the same grant cycle. If a first-year fellow applies for and is awarded a NJCSCR Individual Research Grant, funding will be contingent upon cancellation of the second year of the fellowship. Non-research activities, such as teaching, may not occupy more than 10% of the fellow's time.

Graduate Student Fellowships are two-year awards of \$30,000 per annum. They provide an annual stipend of \$25,000, a research allowance of \$4,000, and a travel budget of \$1,000. No part of this award may be used for institutional overhead, or for tuition. Institutions may supplement stipends, but not with other full-time fellowship awards or other NJCSCR monies.

Applicants must be full-time graduate students in residence in a proposed course of study directly related to regeneration and repair of the damaged spinal cord. Students must begin study in the semester following activation unless special permission is received prior to activation date. The NJCSCR prefers to support graduate student candidates who have completed the first year of graduate study and are concentrating on research projects at least 80% of their time. Applicants may serve as teaching assistants while holding a NJCSCR Graduate Student Fellowship without special permission.

Postdoctoral and Graduate Student Fellowship awards will begin on or about December 15, 2006. Each funding award within the two-year period will be contingent upon the availability of funds. All Postdoctoral and Graduate Student Fellows must submit a first-year Progress Report accompanied by a letter of support from the fellow's mentor. Second-year fellowship funding is contingent upon the successful review of the first-year Progress Report and a recommendation from the mentor. An Evaluation Form must be submitted to the NJCSCR office each year for two years following termination of the Fellowship grant. All forms are available at www.state.nj.us/health/spinalcord.

Successful applicants are offered the opportunity to participate in an approved spinal cord injury techniques course. The NJCSCR will make available up to \$4,000 for a grantee to attend one of the following spinal cord injury techniques courses at: Reeve Irvine Research Center, University of California, Irvine; The Ohio State University; and The W.M. Keck Center for Collaborative Neuroscience, Rutgers, The State University of New Jersey. Grantees are responsible for making all necessary travel and course participation arrangements and payments. Reimbursements will be made to those who provide proof of course completion and expense receipts.

REVIEW PROCESS

All research proposals will be reviewed for scientific merit, technical merit, research significance, and relevance to the NJCSCR priorities by an independent scientific merit review panel. The independent scientific merit review panel will forward its recommendations to the NJCSCR for final review and action. Scientists supported by the NJCSCR are expected to fully report the results of their research to the NJCSCR, and may be asked to report on their results, or work in progress, at a symposium organized by the NJCSCR. Grantees also are expected to acknowledge the support of the New Jersey Commission on Spinal Cord Research in all presentations and publications.

All grant applications must be submitted following the guidelines below. Grant applications that do not adhere to these guidelines will be returned to the applicant without further consideration. Grant applications sent by fax or e-mail will NOT be accepted.

The deadline for all grant applications to be received at the NJCSCR office is 5:00PM on JUNE 8, 2006. No exceptions will be made.

In our effort to reduce paper and speed the process by which grants are awarded, the NJCSCR is introducing an electronic grants submission and review process. All interested grant applicants must submit their applications online through the proposalCENTRAL hosting service.

Applicants in all grant categories must complete an online application and submit five (5) additional hard copies, one of which must be a signed original, to the NJCSCR office, by the deadline as stated above.

Online (electronic) applications for the NJCSCR are now open for preparation and submission of all grant applications. Forms for the various grant programs are available to applicants after they have started an online application in proposalCENTRAL. To start an application for a particular grant category, register and login as a new user at proposalCENTRAL, complete a professional profile, and then click "Apply Now" for the grant category under "Grant Opportunities." Online registration and application are available now at proposalCENTRAL:

<https://v2.ramscompany.com>

Technical support will be provided by proposalCENTRAL during normal business hours 8:30a.m. – 5:00p.m., Monday – Friday, Eastern Time. If you need technical support with your online application, please call 800-875-2562 (toll free) or 301-916-4557 (direct). In addition, e-mail support will be provided at: support@ramscompany.com

NJCSCR Research Program Guidelines governing grants, grant deadlines, progress reports, narrative reports, final narrative reports, and other additional information on the grant program can be viewed and downloaded from the NJCSCR web site at: www.state.nj.us/health/spinalcord/

LETTER OF INTENT

A one-page letter of intent is highly recommended for the "Five-Year Named Chair for Senior and Junior Faculty" grant and for the "One-Time Start-Up Costs" grant. **Letters of intent must be filed with the NJCSCR office by May 3, 2006.** The remaining grant categories do not require a letter of intent.

PROPOSAL SUBMISSION

For all grant categories, applicants must complete an online application and submit five (5) additional hard copies, one of which must be an original (signed), including copies of all reprints, appendices, and any attachments. Applications must be sent to and received by the NJCSCR office no later than 5:00PM, June 8, 2006. **No grant applications will be accepted past this stated deadline.**

Please use this address for all overnight mail deliveries (FedEx, UPS, USPS, Express Mail, etc.):

New Jersey Commission on Spinal Cord Research
Health and Agriculture Building
Warren & Market Streets
4th Floor, Room 404
Trenton, New Jersey 08625

Please use this address for all regular U.S. mail deliveries:

New Jersey Commission on Spinal Cord Research
P.O. Box 360
Health & Agriculture Building
Warren and Market Streets
Trenton, New Jersey 08625

GRANT REVIEW PROCESS

For all grant categories, the determination of grant awards will be made through a three-step review process:

1. **Administrative Review** (NJCSCR office):
Upon receipt, all grant applications will be reviewed by the NJCSCR office for compliance with all applicable New Jersey State statutes and regulations, and to ensure completeness, and accuracy. In the event a grant application needs correction due to a budgetary issue, the applicant will be contacted to provide a revised budget.
2. **Independent Relevance Review** (Appointed Panel):
Independent relevance review will be conducted by a three-person panel appointed by the NJCSCR; members will have varied expertise. The panel will determine the relevance of all applications to the NJCSCR Research Guidelines and assign scientific reviewers for each proposal.

The decision to forward an application for independent scientific merit review is based only on relevance to the NJCSCR mission, priorities, and research guidelines, and does not guarantee that an award will be made.

3. **Scientific Merit Review** (Independent Scientific Merit Review Panel):
Members of the independent scientific merit review panel will convene to evaluate all grant applications, applying the criteria described below. This panel will assign scores to each application and make funding recommendations to the NJCSCR.

If it is determined that *ad hoc* expertise is needed, additional scientific referees may be used.

The Independent Scientific Merit Review Panel will forward its recommendations to the NJCSCR for final review and action.

All grants triaged by either the Relevancy Review Panel and/or the Independent Scientific Merit Review Panel will not be submitted to the NJCSCR, and will not be funded.

The authority to authorize or not authorize grants is fully vested in the NJCSCR according to New Jersey Statute N.J.S.A. 52:9E-1-10.

CRITERIA FOR INDEPENDENT SCIENTIFIC REVIEW

Grant applications will be judged on scientific and technical merit, relevance to the NJCSCR's mission and priorities, clinical relevance, and interdisciplinary collaborations.

The independent scientific reviewers will perform two levels of review:

1. Each panel member will peer review his/her assigned proposals for scientific and technical merit and significance, and determine an initial score for each proposal.
2. The panel will then convene for group discussion, final scoring, and ranking of all proposals; the panel will also recommend a cut-off point for funding.

The following topics will be addressed during the review process:

- Is the research proposal of significance to the field of spinal cord injury research?
- Is the proposed research innovative, including novel concepts, approaches, and/or methods?
- Is the research proposal relevant to NJCSCR priorities?
- Is the research proposal original in theory and application?
- Does prior research and theory provide a rational basis for the proposed research?
- Is the proposed project adequate in terms of experimental design and analyses, anticipation of potential problems, and consideration of alternative approaches?
- Does the researcher have access to appropriate facilities, equipment, expertise, and research environment either in-house and/or with collaborators or consultants?
- Does the design include interdisciplinary collaborations, and if so, is the proposed combination of disciplines both novel and likely to generate meaningful results?
- Are the qualifications, productivity, and time commitments of principal investigator and key staff commensurate with the proposed project?
- If a human model is proposed, is the availability of subjects adequate and system of education and protection of subjects appropriate?
- Is there evidence of compliance with National Institutes of Health regulations for the protection of animal welfare?
- Is the justification for procedures assessing the effects of interventions on recovery recognized, standardized, and generally accepted?
- Is the budget reasonable and justified for the project proposed? Is there evidence of institutional commitment and/or cost sharing in the proposal?
- Are there other factors both pro and con, that may affect the ability of the applicant to successfully complete the research goals?
- Will the project make an original and important contribution to the field of spinal cord research and more specifically, to the mission of the NJCSCR?

RESULTS NOTIFICATION

All applicants including Principal Investigators and organizations/institutions will be formally notified of the outcome of his/her application at the conclusion of the selection process anticipated to be no later than November 30, 2006. At that time, formal notification will be made to the institutions of successful applicants and contracts will be initiated shortly thereafter.

Blinded reviews will be provided to both funded and non-funded applicants; no further information shall be provided.

Non-funded applicants also will be notified. There is no appeal process. All non-funded applicants in any given grant cycle who are not funded are eligible to revise their applications based on reviewer feedback and reapply, one time only, through the reapplication process. All scored-but-not-funded applications may be resubmitted within 30 days (5:00PM on December 29, 2006) or at the next application cycle (5:00PM on June 8, 2007). Applications that are triaged may only be resubmitted once, at the next application cycle (5:00PM on June 8, 2007), and only if the applicant has substantively responded to the major criticisms of the review panel. All reapplications will be reviewed as new competing proposals.

ANTICIPATED RESULTS

The goal of the NJCSCR is to assume a catalytic role in the worldwide movement to develop effective interventions and cures for paralysis and other consequences of spinal cord injury and disease.

Through the judicious use of funds raised through violations under Title 39 of the Revised Statute, or any other motor vehicle, or traffic violation in the State of New Jersey, the NJCSCR will encourage and support meritorious scientific research in the State of New Jersey in fulfillment of that goal.

This will benefit the State of New Jersey in savings on medical and support costs, enhance the development of the State's public and private biomedical sector, establish leadership in the field of spinal cord repair, and most importantly, help develop effective interventions for paralysis and other consequences of spinal cord injury and disease.